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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/976,673	10/12/2001	Sergey Lukyanov	CLON-028	1096
41064	7590	06/01/2005	EXAMINER	
BOZICEVIC, FIELD & FRANCIS (BD BIOSCIENCES)			MONDESI, ROBERT B	
1900 UNIVERSITY AVENUE			ART UNIT	
SUITE 200			PAPER NUMBER	
EAST PALO ALTO, CA 94303			1653	

DATE MAILED: 06/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	09/976,673		LUKYANOV ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Robert B. Mondesi		1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 March 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 18-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 18-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

*[Handwritten signature]*

### **DETAILED ACTION**

This Office action is in response to the amendment filed March 22, 2005. **Claims 13-17** have been canceled. **Claims 20-24** are new. **Claims 1-12 and 18-24** as drawn to elected Invention I are currently pending and are under examination. Applicants are also reminded of the further election of SEQ ID No: 11, that was made in response filed on June 01, 2004 and because applicants did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Therefore the requirement is deemed proper and is made FINAL. Elected **claims 5-12, and 18-27** are presently examined only to the degree that they will pertain to patentably distinct elected nucleic acid sequence molecule designated as SEQ ID No: 11

#### ***Withdrawal of Objections and Rejections***

The objection of **claim 1,7-10, 12, 18-19** because of an informality is withdrawn.

#### ***Maintenance of rejections***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

**Claims 1-2, 7-12 and 18-19** remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection was explained in the previous Office action.

**Claim 8** remains rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

This rejection was explained in the previous Office action.

### ***Double Patenting***

**Claims 1-2, 7-12 and 18-19** remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over **claims 1-5, 8-10, 12-15, 22-23** of copending Application No. 10/006922.

This rejection was explained in the previous Office action.

**Claims 1-2, 7-12 and 18-19** remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over **claims 1-3, 5-9 and 15-16** of copending Application No. 10/081864.

This rejection was explained in the previous Office action.

**Claims 1-12 and 18-19** remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over **claims 1-16, 21 and 43** of copending Application No. 10155809. This rejection was explained in the previous Office action.

***Response to applicant's arguments***

In view of the rejection of **claims 1-2, 7-12 and 18-19** under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, the applicants urge that the specification provides multiple representative examples, including working examples of representative nucleic acids encoding exemplary mutant proteins, such that one of skill in the art would have no doubt that the applicant was in possession of the invention as claimed at the time the application was filed.

Applicants urge further that "the law is clear that, if a person of ordinary skill in the art would have understood the inventor to have possession of the claimed invention at the time of filing, even if not every nuance of the claims is explicitly described in the specification, then the adequate written description requirement is met. Furthermore, the applicants state that the specification provides working examples demonstrating exemplary mutagenesis protocols for generating the subject nucleic acids encoding the far red shifted *Stichodactylidaen* chromoprotein or fluorescent mutants thereof.

The applicants also maintain that by showing specific examples of nucleic acids encoding far red shifted *Stichodactylidaen* chromoprotein or fluorescent mutants thereof, as well as providing a thorough description of DNA mutagenesis methods suitable for use with the present application they have provided adequate written description support for the scope of the claims.

Applicants' arguments have not been found persuasive. It must be noted to the applicants that the disclosure in the art can enable applicants' specification, however, it does not provide missing written description. The reason behind the present written description rejection is that the scope of the claims encompass mutants and fragments that have not been adequately described, thus the applicants were not in possession of the claimed invention. The claims broadly read on mutations that result from substitutions, additions/insertion, etc., throughout the protein structure with no size limitations and no indication of a conserved region. Therefore, applicants' statement that the written description provided supports the scope of the claim, presently, is not necessarily accurate. Furthermore, Page 15 of the instant specification indicates that a deletion of stretches such as 10,20,50,75,100, 150 or more is contemplated; therefore the claims encompass a large genus of mutants, which have not been adequately described. The instant specification fails to provide a representative number of species by actual reduction to practice, disclosure of drawings of relevant identifying characteristics, for example, structure or other physical/ and or chemical properties nor is there any disclosure of what structural features might be responsible for the shift to far red, no written description of where to mutate the protein ...(see MPEP 2163).

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Hence, the skilled artisan cannot envision the detailed chemical structure of the encompasses genus of polypeptide mutants and can not reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Furthermore, it has long been known how to mutate proteins, but it has similarly been long known that such mutations are not reasonably predictive of activity for any particular protein. For example, Rudinger (1976) Peptide Hormones, University Park Press, Baltimore, MD., pp. 1-7 discusses the peptide hormones and the characteristics of amino acids as components of the peptide hormones (TITLE). (It is noted that Rudinger discusses peptide hormones, but the general areas of unpredictability are common to all proteins.) In doing so, Rudinger notes that many amino acids may be grouped according to general characteristic (pp. 1-3), and many of these are also classified in two or more classifications (p. 3). Hence, simple mutations of "type" are not reasonably predictable, because there are multiple types to any particular amino acid. Moreover, Rudinger finds that the context of any amino acid is important for structure (pp. 3-4), and that therefore, simple deletions, insertions, or substitutions are also not reasonably predictable, because not only is "type" important, but context is also important, having longer-range effects than that of simply type. Further, Rudinger discusses the mechanisms of information transfer (e.g, binding and effecting a receptor, which is analogous to any protein binding anything and causing any particular effect) (pp. 4-5). In doing so, Rudinger finds that there exist "patterns" on molecules for recognition, which may involve amino acids close by in the amino-acid polypeptide

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sequence, or far away (Id.). As such the conformation of the whole molecule is important, and any particular amino acid change, deletion, or addition, may alter the conformation of the molecule enough to affect any particular binding and effect on another molecule.

In analyzing the significance of such observations, Rudinger states that: In a given molecule, some amino acids or sequences obviously owe their 'significance' to their inclusion in the pattern which is directly involved in recognition by, and binding to, the receptor. However, the fact that the existence of this pattern is dependent on a conformation stabilized by intramolecular interactions, ..., implies that other amino acids or sequences contributing to this conformational stability will be no less 'significant' for the biological activity of the molecule.

(p. 5).

And, in conclusion, Rudinger states:

The significance of particular amino acids and sequences for different aspects of biological activity cannot be predicted *a priori* but must be determined from case to case by painstaking experimental study. The careful design of synthetic analogues, and their evaluation in biological systems which permit separate analysis of the various phases of hormone action, is the best way to obtaining such information.

(p. 6).

Bowie, et al. (1990) Science, 247 : 1306-10 provides similar insight into the lack of reasonable predictability for the mutation of any particular protein. To wit, Bowie discusses that while many substitutions may be tolerated, in other cases substitutions may not be tolerated at all (e.g., 1306, col. 2, paragraph 2). Moreover, the significance of surface and buried amino acids while is not reasonably predictable either (pp. 1306-07), surface sites may not have any importance, but sometimes they are absolutely important due to binding (p. 1308), and predicting structure with reasonable predictability is generally limited to homologous proteins, but even that is difficult due to



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alignment problems (p. 1308). In general, Bowie continues to reflect the observations of Rudinger: it is not reasonably predictable that any particular amino acid change, deletion, or addition would provide a functional molecule with similar activity, and only painstaking analysis would provide such information for any particular change (e.g., pp. 1309-10).

Hence, the nature of the invention is not reasonably predictable for any of the particular proteins and genes claimed, due to the unpredictability of structure-function relationships.

In regards to the rejection of **Claim 8** under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, the applicants state that they have amended the claims in order to include the phrase "at least as stringent as hybridization at about 50°C and about 0.1SSC".

Applicants' assertion has not been found persuasive. Simply put, "at least as stringent as hybridization at about 50°C and about 0.1SSC" is by no means a sufficient stringent condition. The applicants' have used the relative term about with the most minimal set of conditions defined in the specification as stringent. Under presently stated condition the probability of non-specific binding of unrelated nucleic acid molecules is extremely high; therefore the applicants have not shown to a person skill in the art how to use the stringent conditions in order to hybridize the said nucleic acid molecule with any specific nucleic acid molecule.

In regards to the rejection of **Claims 1-2, 7-12 and 18-19** under the judicially created doctrine of obviousness-type double patenting as being unpatentable over

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**claims 1-3, 5-9 and 15-16** of copending Application No. 10/006,922, the applicants urge further that the cited reference is silent as far as red shifted *Stichodactylidian* chromoprotein or fluorescent protein.

Applicant's arguments have not been found persuasive. In response the examiner would like to direct the applicants' attention to Page 15, Lines 9-11, wherein it is clearly stated that the emission spectra of the subject proteins typically ranges from 400-800 nm, which is well into the far red region. Also, it must be pointed out that **claim 3** of the present application specifically states that the nucleic acid molecules of the invention encode fluorescent proteins that have an emission maximum ranging from 620-680.

In regards to the rejection of **Claims 1-2, 7-12 and 18-19** under the judicially created doctrine of obviousness-type double patenting as being unpatentable over **claims 1-3, 5-9 and 15-16** of copending Application No. 10/081864, the applicants state the claims of the present application are directed to nucleic acids encoding a far red shifted *Stichodactylidian* chromoprotein or fluorescent mutant thereof and in contrast the copending 864 application is directed to nucleic acids encoding non-aggregating chromo- or fluorescent mutants of an aggregating *Cnidarian* chromo-or- fluorescent protein or mutant thereof. The applicants urge further that the cited reference is silent as far as red shifted *Stichodactylidian* chromoprotein or fluorescent protein.

Applicant's arguments have not been found persuasive. With all due respect to the applicants and even though the applicants are allowed to be their own

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lexicographer, the examiner must point out that according to present day taxonomy *Cnidarian* are sea anemones which are a family of the phylum *Cnidaria*, which comprises such invertebrate animals as corals, jellyfish and as mentioned sea anemones; furthermore in the specification of pending application 10/081864 it clearly states in Page 17, Line 27-28, that the emission spectra of the subject proteins typically ranges from 400-800 nm, which is well into the far red region. Also, it must be pointed out that **claim 3** of the present application specifically states that the nucleic acid molecules of the invention encode fluorescent proteins that have an emission maximum ranging from 620-680.

In regards to the rejection of **Claims 1-2, 7-12 and 18-19** under the judicially created doctrine of obviousness-type double patenting as being unpatentable over **claims 1-3, 5-9 and 15-16** of copending Application No. 10/155,809, the applicants urge further that the cited reference is silent as far as red shifted *Stichodactylidian* chromoprotein or fluorescent protein.

In response the examiner would like to direct the applicants' attention to Page 15, Lines 9-11, wherein it is clearly stated that the emission spectra of the subject proteins typically ranges from 400-800 nm, which is well into the far red region. Also, it must be pointed out that **claim 3** of the present application specifically states that the nucleic acid molecules of the invention encode fluorescent proteins that have an emission maximum ranging from 620-680.

***New rejection(s)***

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

**Claims 20-24** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claimed invention is directed to a nucleic acid molecule that encodes a *Stichodactylidiaen* chromoprotein or fluorescent mutant thereof, however, the claimed nucleic acid is only defined by a function (encoding a protein) not a structure, for example see **claims 20-24**. In addition, the encoded protein is a mutant of *Stichodactylidiaen* chromoprotein or fluorescent protein mutant thereof (see for example **claim 20**) and the claim does not define a reference point for the mutation as the protein is defined solely by its properties. The claims encompass a genus of mutants not adequately described in the instant specification. For example, on page 8 of the instant specification it is stated that nucleic acids encoding mutants of the proteins can be generated by random mutagenesis using well known techniques in the art. The mentioned techniques may produce sequence changes that may be substitutions, insertions, deletions, or a combination thereof. Deletions may further include larger

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changes such as deletions of a domain or exon, for example stretches of 10, 20, 50, 75, 100, 150 or more amino acid residues presenting a genus of species that have not been adequately described in the present application. A person skill in the art would not be able to readily predict random mutations and envision the detailed chemical structure of the genus of polypeptide mutants.

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, disclosure of drawings, or by disclosure of relevant identifying characteristics, for example, structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus.

*Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111, clearly states, "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the "written description" inquiry, whatever is now claimed." (See page 1117.) The specification does not it clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116), As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is

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part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore for all of these reasons the specification lacks adequate written description, and one skill in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Furthermore, it has long been known how to mutate proteins, but it has similarly been long known that such mutations are not reasonably predictive of activity for any particular protein. For example, Rudinger (1976) *Peptide Hormones*, University Park Press, Baltimore, MD., pp. 1-7 discusses the peptide hormones and the characteristics of amino acids as components of the peptide hormones (TITLE). (It is noted that Rudinger discusses peptide hormones, but the general areas of unpredictability are common to all proteins.) In doing so, Rudinger notes that many amino acids may be grouped according to general characteristic (pp. 1-3), and many of these are also classified in two or more classifications (p. 3). Hence, simple mutations of "type" are not reasonably predictable, because there are multiple types to any particular amino acid. Moreover, Rudinger finds that the context of any amino acid is important for structure (pp. 3-4), and that therefore, simple deletions, insertions, or substitutions are also not

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reasonably predictable, because not only is “type” important, but context is also important, having longer-range effects than that of simply type. Further, Rudinger discusses the mechanisms of information transfer (e.g, binding and effecting a receptor, which is analogous to any protein binding anything and causing any particular effect) (pp. 4-5). In doing so, Rudinger finds that there exist “patterns” on molecules for recognition, which may involve amino acids close by in the amino-acid polypeptide sequence, or far away (Id.). As such the conformation of the whole molecule is important, and any particular amino acid change, deletion, or addition, may alter the conformation of the molecule enough to affect any particular binding and effect on another molecule.

In analyzing the significance of such observations, Rudinger states that: In a given molecule, some amino acids or sequences obviously owe their ‘significance’ to their inclusion in the pattern which is directly involved in recognition by, and binding to, the receptor. However, the fact that the existence of this pattern is dependent on a conformation stabilized by intramolecular interactions, ..., implies that other amino acids or sequences contributing to this conformational stability will be no less ‘significant’ for the biological activity of the molecule.

(p. 5).

And, in conclusion, Rudinger states:

The significance of particular amino acids and sequences for different aspects of biological activity cannot be predicted *a priori* but must be determined from case to case by painstaking experimental study. The careful design of synthetic analogues, and their evaluation in biological systems which permit separate analysis of the various phases of hormone action, is the best way to obtaining such information.

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Bowie, et al. (1990) Science, 247 : 1306-10 provides similar insight into the lack of reasonable predictability for the mutation of any particular protein. To wit, Bowie

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discusses that while many substitutions may be tolerated, in other cases substitutions may not be tolerated at all (e.g., 1306, col. 2, paragraph 2). Moreover, the significance of surface and buried amino acids while is not reasonably predictable either (pp. 1306-07), surface sites may not have any importance, but sometimes they are absolutely important due to binding (p. 1308), and predicting structure with reasonable predictability is generally limited to homologous proteins, but even that is difficult due to alignment problems (p. 1308). In general, Bowie continues to reflect the observations of Rudinger: it is not reasonably predictable that any particular amino acid change, deletion, or addition would provide a functional molecule with similar activity, and only painstaking analysis would provide such information for any particular change (e.g., pp. 1309-10).

Hence, the nature of the invention is not reasonably predictable for any of the particular proteins and genes claimed, due to the unpredictability of structure-function relationships.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double



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patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

**Claims 20-24** are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over **claims 1-5, 8-10, 12-15, 22-23** of copending Application No. 10/006922. Although the conflicting claims are not identical, they are not patentably distinct from each other because **claims 20-24** of the present application are drawn to a nucleic acid molecule that encodes a *Stichodactylidiaen* chromoprotein or fluorescent mutant thereof. *Stichodactylidiaen* is a family of organisms that is in the class *Anthozoa* which is in the phylum *Cnidaria*. **Claims 1-5, 8-10, 12-15 and 22-23** of copending application No. 10/006922 are drawn to a nucleic acid molecule that encodes a *Cnidarian* chromoprotein or fluorescent mutant thereof.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

**Claims 20-24** are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over **claims 1-3, 5-9 and 15-16** of copending Application No. 10/081864. Although the conflicting claims are not identical, they are not patentably distinct from each other because **claims 20-24** of the present application are drawn to a nucleic acid molecule that encodes a *Stichodactylidiaen* chromoprotein or fluorescent mutant thereof. *Stichodactylidiaen* is a family of organisms that is in the class *Anthozoa* that is in the phylum *Cnidaria*. **Claims**

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**1-3, 5-9 and 15-16** of copending application No. 10/081864 are drawn to a nucleic acid molecule that encodes a *Cnidarian* chromoprotein or fluorescent mutant thereof.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

**Claims 20-24** are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over **claims 1-16, 21 and 43** of copending Application No. 10155809. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application are directed to nucleic acids encoding far-red shifted *Anthozoan* chromoproteins or fluorescent proteins, whereas the scope of the instant claims is to nucleic acids encoding any kindling fluorescent proteins. The instant claims overlap and encompass those sections of the claims of the copending application, which are directed to fluoroproteins.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

**No claims are allowed.**

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

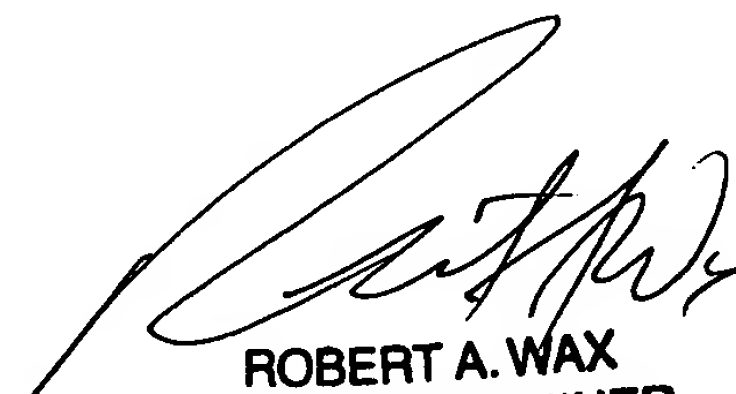
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert B Mondesi whose telephone number is 571-272-0956. The examiner can normally be reached on 9am-5pm, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert B. Mondesi  
Patent Examiner  
Group 1653

  
05-26-05

  
ROBERT A. WAX  
PRIMARY EXAMINER  
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